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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,026	08/11/2005	Hideaki Yamaoka	10921.0286USWO	4688

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EXAMINER	
MEAH, MOHAMMAD Y	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,026	YAMAOKA ET AL.	
	Examiner	Art Unit	
	MD. YOUNUS MEAH	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/9/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9,11-14 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-9,11-14 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 6-9, 11-14 and 24-26 are currently pending in the instant application.

In response to a previous office action, a non-final action, mailed on 02/09/2009, Applicants' on 06/09/09 amended claims 1 and 7-9.

Applicants' response of 06/09/09 is acknowledged. Claims 1, 6-9, 11-14 and 24-26 are under consideration. Applicants' arguments filed on 06/09/09 have been fully considered but they are found unpersuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim rejection 35 U.S.C 103a

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-9, 11-14 and 24-26 were rejected under 35 U.S.C. 103(b) by Shimomura et al (Anal biochem, 1986, vol. 153, pp 126-131) in view of Sode et al. (WO 02/36779, English translation in US 2004/0023330) and Amersham catalog 1999, pages 520, 523 and 527). This rejection is maintained as discussed at length in the previous office action and discussed it again.

Claims 1, 6-9, 11-14 and 24-26 are directed to the purification of *Burkholderia* glucose dehydrogenase (GDH) protein comprising α, β, γ subunits using liquid

chromatography comprising ion exchange (resin comprising quaternary ammonium group) and using eluent containing cholate.

Shimomura et al teach the purification of Cytochrome bc (a protein having electron transfer and GDH unit) protein using liquid chromatography comprising phenyl-sepharose and ion exchange (DEAE; diethylaminoethyl) sepharose column, wherein eluent is applied at constant gradient containing 0.25% cholate (abstract, Na cholate, cholate in a solution comprising NaCl).

Sode et al teach isolation of GDH protein from microorganism *Burkholderia Cepacia* comprising α, β, γ subunit and teaches expression of said protein in *E. coli* and the purification of said GDH protein by ion-exchange chromatography using DEAE-Toyopearl column using a buffer at pH 8.0 (paragraphs 0154-0175). However, Sode et al. do not teach the elution of said protein from the column with a cholate nor teach chromatography using quaternary ammonium group comprising tetra-alkyl or tetra-aryl substituted ammonium ion exchanger.

Ion exchange resin comprising quaternary ammonium moiety, such as Q-sepharose (packing agent comprising a quaternary ammonium moiety) is commercially available from Amaersham (see Amersham Catalog 1999, page 523). Advantageous use of Q-sepharose as an anion exchanger in protein purification is well documented, such as high flow, high capacity, wide range of pH, reproducibility, industrial scale application and commercial availability (see catalog Amersham 1999, pages 520, 523). Therefore Q-sepharose column has advantages over other DEAE column, such as wide

pH ranges, high resolution, and high capacity for the protein to be separated in high salt concentration.

Cholate is used as eluent for the purification of different cytochrome type proteins (such as glucose dehydrogenase (GDH)) because it facilitates hydrophobic-interaction and behaves as detergent. Protein is adsorbed in the column matrix and cholate act as detergent to dissolve it (see Imai et al J. Biochem 1976, pp 267-276, page 274 from IDS, Shimomura et al Abstract).

It is well known in art that glucose dehydrogenases are biologically important compounds (paragraphs 2-15, 242 Sode et al.). One of ordinary skill in art is **motivated** to combine the teaching of Shimomura et al, and Sode et al. and use the Q-sepharose (ion exchange resin comprising quaternary ammonium moiety) as a packing agent and cholate as an eluting agent in the liquid chromatographic separation procedure of Sode et al. to purify efficiently GDH protein comprising α, β, γ subunit in large scale.

As such it would have been obvious to one of ordinary skill in the art to obtain GDH protein comprising α, β, γ subunit from microorganism *Burkholderia Cepacia* or said GDH produced by transformant such as *E. coli* taught by Sode use the method of purification using ion exchange column with Q-sheparose, wherein eluent is applied at constant gradient containing 0.25% cholate (a high salt concentration Q sepharose is preferred, instead of sodium chloride) as taught by Shimomura et al.

Arguments and response

Applicants' argue, at page 5-7 of their amendment of 06/ 09/09, that the purification of GDH protein comprising α, β, γ subunit using ion exchange column with

quaternary ammonium ion-exchanger and cholate solution as an eluent would be considered a surprising result to those of skill in the art and applicant is the first found the surprising result. Applicants' argue that none of the three references teach purifying GDH protein comprising α, β, γ subunit of *Burkholderia* using an ion-exchange resin containing a quaternary ammonium group as an ion-exchange group and eluting agent comprising cholate.

Applicants' arguments files on 06/ 09/09, have been fully considered, but they found unpersuasive. There is nothing surprising or unexpected for purifying GDH protein comprising α, β, γ subunit using ion exchange column with quaternary ammonium ion-exchanger and cholate as an eluent. Many proteins and enzymes have been purified by liquid chromatographic procedure using quaternary ammonium ion-exchanger (Q-sheparose, Amersham Catalog 1999) using variety of eluents. Applicants argument that none of the references disclose purifying GDH protein comprising α, β, γ subunit using ion exchange column with quaternary ammonium ion-exchanger and cholate as eluent, if they do the would anticipate the applicants invention. However as indicated above, the three references provide the teaching and the state of the prior art as well as the expectation of success to purify GDH protein comprising α, β, γ subunit using ion exchange column with quaternary ammonium ion-exchanger (Q-sheparose) and cholate as eluent. Applicants argument that none of the prior art uses sodium cholate as an eluting agent is not true. Shimomura et al teach the purification of Cytochrome bc protein using liquid chromatography wherein eluent is

applied at constant gradient containing 0.25% cholate and .25% NaCl solution which comprises sodium cholate solution (abstract,).

Applicants have provided no evidence or a reasonable scientific argument to support surprising or unexpected results. Thus, the claimed invention remains *prima fasciae* obvious over the prior art of record.

Conclusion

Claims 1, 6-9, 11-14 and 24-26 are rejected. No claim is allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah
Examiner, Art Unit 1652

/Andrew Wang/

Supervisory Patent Examiner, Art Unit 1656